

**Form 10 & 50 - HRT Management and Safety Interview, Report of Vaginal Bleeding****Data File:** f10\_50\_ep\_fu\_pub **File Date:** 07/18/2005 **Structure:** Multiple rows per participant **Population:** E+P participants**Participant ID****Variable #** 1**Usage Notes:** none**Sas Name:** ID**Categories:** Study: Administration**Sas Label:** Participant ID**F10/50 Days since randomization**

Days between randomization and initiation of form

**Variable #** 2**Usage Notes:** none**Sas Name:** F1050DYS**Categories:** Study: Administration**Sas Label:** F10/50 Days since randomization

| N      | Min | Max  | Mean      | Std Dev  |
|--------|-----|------|-----------|----------|
| 169589 | 2   | 3126 | 943.39505 | 672.8466 |

**F10/50 Visit Type****Variable #** 3**Usage Notes:** none**Sas Name:** F1050VTYP**Categories:** Study: Administration**Sas Label:** Visit Type

| Values                  | N       | %     |
|-------------------------|---------|-------|
| 1 Screening Visit       | 0       | 0.0%  |
| 2 Semi-Annual Visit     | 76,865  | 45.3% |
| 3 Annual Visit          | 70,050  | 41.3% |
| 4 Non-Routine Visit     | 6,777   | 4.0%  |
| 5 6-Week HRT Phone Call | 15,897  | 9.4%  |
|                         | 169,589 |       |

**F10/50 Visit number**

Number of the visit for which this form was collected.

**Variable #** 4**Usage Notes:** none**Sas Name:** F1050VNUM**Categories:** Study: Administration**Sas Label:** Visit Number

| N      | Min | Max | Mean    | Std Dev |
|--------|-----|-----|---------|---------|
| 146915 | 1   | 9   | 3.15128 | 1.7371  |

**Had a hysterectomy**

Has the participant had a hysterectomy?

**Variable #** 5**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Sas Name:** HYST**Categories:** Medical History: Reproductive**Sas Label:** Had a hysterectomy

| Values    | N       | %     |
|-----------|---------|-------|
| 0 No      | 160,754 | 94.8% |
| 1 Yes     | 1,807   | 1.1%  |
| . Missing | 7,028   | 4.1%  |
|           | 169,589 |       |



Form 10 & 50 - HRT Management and Safety Interview, Report of Vaginal Bleeding

Data File: f10\_50\_ep\_fu\_pub File Date: 07/18/2005 Structure: Multiple rows per participant Population: E+P participants

Had vaginal bleeding

Variable # 6

Sas Name: VAGBLEED

Sas Label: Had vaginal bleeding

Usage Notes: none

Categories: Reproductive: Menstrual

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 142,323 | 83.9% |
| 1      | Yes     | 25,767  | 15.2% |
| .      | Missing | 1,499   | 0.9%  |
|        |         | 169,589 |       |

How heavy was vaginal bleeding

Variable # 7

Sas Name: HEAVYBLD

Sas Label: How heavy was vaginal bleeding

Usage Notes: Not collected on all versions of Form 10.

Categories: Reproductive: Menstrual

| Values |                             | N       | %     |
|--------|-----------------------------|---------|-------|
| 1      | Spotting - approx 1 pad/day | 18,467  | 10.9% |
| 2      | Light - 2 or 3 pads/day     | 3,200   | 1.9%  |
| 3      | Moderate - 4 to 7 pads/day  | 2,315   | 1.4%  |
| 4      | Severe - 8 or more pads/day | 330     | 0.2%  |
| .      | Missing                     | 145,277 | 85.7% |
|        |                             | 169,589 |       |

Days from randomization to vaginal bleeding start

Variable # 8

Sas Name: STARTDY

Sas Label: Days from randomization to vaginal bleeding start

Usage Notes: Not collected on all versions of Form 10.

Categories: Reproductive: Menstrual

| N     | Min  | Max  | Mean     | Std Dev   |
|-------|------|------|----------|-----------|
| 23824 | -350 | 3042 | 537.6438 | 600.66759 |

Did vaginal bleeding start and stop again

Variable # 9

Sas Name: INTERMIT

Sas Label: Did vaginal bleeding start and stop again

Usage Notes: Not collected on all versions of Form 10.  
Not collected on all versions of Form 50.

Categories: Reproductive: Menstrual

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 7,451   | 4.4%  |
| 1      | Yes     | 16,458  | 9.7%  |
| .      | Missing | 145,680 | 85.9% |
|        |         | 169,589 |       |

**Form 10 & 50 - HRT Management and Safety Interview, Report of Vaginal Bleeding****Data File:** f10\_50\_ep\_fu\_pub **File Date:** 07/18/2005 **Structure:** Multiple rows per participant **Population:** E+P participants

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**Are you bleeding from the vagina now****Variable #** 10**Sas Name:** BLEEDNOW**Sas Label:** Are you bleeding from the vagina now**Usage Notes:** Not collected on all versions of Form 10.**Categories:** Reproductive: Menstrual

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 19,837  | 11.7% |
| 1      | Yes     | 4,594   | 2.7%  |
| .      | Missing | 145,158 | 85.6% |
|        |         | 169,589 |       |

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**Days from randomization to vaginal bleeding stop****Variable #** 11**Sas Name:** STOPDY**Sas Label:** Days from randomization to vaginal bleeding stop**Usage Notes:** Not collected on all versions of Form 10.  
Sub-question of "Are you bleeding from the vagina now".**Categories:** Reproductive: Menstrual

| N     | Min  | Max  | Mean      | Std Dev   |
|-------|------|------|-----------|-----------|
| 18444 | -327 | 3098 | 609.67729 | 598.56785 |

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**Had any breast tenderness**

Since your last contact, have you had any breast tenderness?

**Variable #** 12**Sas Name:** BRSTTEND**Sas Label:** Had any breast tenderness**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Breast

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 49,851  | 29.4% |
| 1      | Yes     | 4,358   | 2.6%  |
| .      | Missing | 115,380 | 68.0% |
|        |         | 169,589 |       |

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**Breast tenderness severity**

Was your breast tenderness mild, moderate, or severe?

**Variable #** 13**Sas Name:** SEVTEND**Sas Label:** Breast tenderness severity**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.  
Sub-question of F10 V7 Q7 "Had any breast tenderness"**Categories:** Medical History: Breast

| Values |          | N       | %     |
|--------|----------|---------|-------|
| 1      | Mild     | 3,334   | 2.0%  |
| 2      | Moderate | 763     | 0.4%  |
| 3      | Severe   | 177     | 0.1%  |
| .      | Missing  | 165,315 | 97.5% |
|        |          | 169,589 |       |

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**Any changes in your breasts**

Have you noticed any changes in your breasts (new lumps, nipple discharge, or skin changes)?

**Variable #** 14**Usage Notes:** Not collected on Form 50.**Sas Name:** BRSTCHNG**Categories:** Medical History: Breast**Sas Label:** Any changes in your breasts

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 160,681 | 94.7% |
| 1      | Yes     | 5,471   | 3.2%  |
| .      | Missing | 3,437   | 2.0%  |
|        |         | 169,589 |       |

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**Taking or prescribed Corticosteroids**

Are you now taking, or has a doctor prescribed, any Corticosteroids (such as Prednisone, Decadron, Medrol in pill form)?

**Variable #** 15**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Sas Name:** CORTICOS**Categories:** Medical History: Medications**Sas Label:** Taking or prescribed Corticosteroids

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 150,192 | 88.6% |
| 1      | Yes     | 1,400   | 0.8%  |
| .      | Missing | 17,997  | 10.6% |
|        |         | 169,589 |       |

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**Taking or prescribed blood thinning medications**

Are you now taking, or has a doctor prescribed any blood thinning medications (such as Coumadin or Warfarin)?

**Variable #** 16**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Sas Name:** ANTICOAG**Categories:** Medical History: Medications**Sas Label:** Taking or prescribed blood thinning medications

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 150,007 | 88.5% |
| 1      | Yes     | 1,461   | 0.9%  |
| .      | Missing | 18,121  | 10.7% |
|        |         | 169,589 |       |

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**Taking or prescribed Estrogen**

Are you now taking, or has a doctor prescribed Estrogen?

**Variable #** 17**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Sas Name:** ESTROGEN**Categories:** Medical History: Medications  
Reproductive: Hormones**Sas Label:** Taking or prescribed Estrogen

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 148,938 | 87.8% |
| 1      | Yes     | 2,613   | 1.5%  |
| .      | Missing | 18,038  | 10.6% |
|        |         | 169,589 |       |

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**Taking or prescribed Progesterone**

Are you now taking, or has a doctor prescribed Progesterone?

**Variable #** 18**Sas Name:** PROGEST**Sas Label:** Taking or prescribed Progesterone**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Medications  
Reproductive: Hormones

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 149,589 | 88.2% |
| 1      | Yes     | 1,951   | 1.2%  |
| .      | Missing | 18,049  | 10.6% |
|        |         | 169,589 |       |

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**Taking or prescribed Testosterone**

Are you now taking, or has a doctor prescribed Testosterone?

**Variable #** 19**Sas Name:** TESTOST**Sas Label:** Taking or prescribed Testosterone**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Medications  
Reproductive: Hormones

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 151,323 | 89.2% |
| 1      | Yes     | 112     | 0.1%  |
| .      | Missing | 18,154  | 10.7% |
|        |         | 169,589 |       |

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**Taking or prescribed Tamoxifen**

Are you now taking, or has a doctor prescribed Tamoxifen, Raloxifene (Evista) or other medications know as SERMS?

**Variable #** 20**Sas Name:** TAMOXIF**Sas Label:** Taking or prescribed Tamoxifen**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Medications  
Reproductive: Hormones

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 150,769 | 88.9% |
| 1      | Yes     | 659     | 0.4%  |
| .      | Missing | 18,161  | 10.7% |
|        |         | 169,589 |       |

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**Endometrial hyperplasia**

Since your last contact has a doctor told you that you had Endometrial hyperplasia?

**Variable #** 21**Sas Name:** ENDOHYP**Sas Label:** Endometrial hyperplasia**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Reproductive

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 151,265 | 89.2% |
| 1      | Yes     | 151     | 0.1%  |
| .      | Missing | 18,173  | 10.7% |
|        |         | 169,589 |       |

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**Form 10 & 50 - HRT Management and Safety Interview, Report of Vaginal Bleeding****Data File:** f10\_50\_ep\_fu\_pub **File Date:** 07/18/2005 **Structure:** Multiple rows per participant **Population:** E+P participants**High triglycerides in blood**

Since your last contact has a doctor told you that you had high triglycerides in your blood (triglycerides are not the same as cholesterol)?

**Variable #** 22**Sas Name:** HIGHTRIG**Sas Label:** High triglycerides in blood**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Other Disease/Condition

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 148,766 | 87.7% |
| 1      | Yes     | 2,596   | 1.5%  |
| .      | Missing | 18,227  | 10.7% |
|        |         | 169,589 |       |

**Were your triglycerides over 1000 (mg/dl)****Variable #** 23**Sas Name:** TRIG1000**Sas Label:** Were your triglycerides over 1000 (mg/dl)**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.  
Sub-question of F10 V7 Q11.2 "High triglycerides in blood".**Categories:** Medical History: Other Disease/Condition

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 1,427   | 0.8%  |
| 1      | Yes     | 11      | 0.0%  |
| .      | Missing | 168,151 | 99.2% |
|        |         | 169,589 |       |

**Blood clot to your leg or lung**

Since your last contact has a doctor told you that you had a blood clot to your leg or lung?

**Variable #** 24**Sas Name:** BLDCLOT**Sas Label:** Blood clot to your leg or lung**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Cardiovascular

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 151,153 | 89.1% |
| 1      | Yes     | 353     | 0.2%  |
| .      | Missing | 18,083  | 10.7% |
|        |         | 169,589 |       |

**Melanoma of skin**

Since your last contact has a doctor told you that you had melanoma of skin?

**Variable #** 25**Sas Name:** MELANOMA**Sas Label:** Melanoma of skin**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Cancer

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 151,407 | 89.3% |
| 1      | Yes     | 88      | 0.1%  |
| .      | Missing | 18,094  | 10.7% |
|        |         | 169,589 |       |

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**Heart attack or stroke**

Since your last contact has a doctor told you that you had a heart attack or stroke?

**Variable #** 26**Sas Name:** HEARTSTK**Sas Label:** Heart attack or stroke**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Cardiovascular

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 150,927 | 89.0% |
| 1      | Yes     | 538     | 0.3%  |
| .      | Missing | 18,124  | 10.7% |
|        |         | 169,589 |       |

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**Meningioma, or tumors in the brain**

Since your last contact has a doctor told you that you had meningioma, or tumors in the brain?

**Variable #** 27**Sas Name:** MENINGIO**Sas Label:** Meningioma, or tumors in the brain**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Cancer

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 151,327 | 89.2% |
| 1      | Yes     | 81      | 0.0%  |
| .      | Missing | 18,181  | 10.7% |
|        |         | 169,589 |       |

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**Breast cancer**

Since your last contact has a doctor told you that you had breast cancer?

**Variable #** 28**Sas Name:** BRSTCANC**Sas Label:** Breast cancer**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Cancer

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 53,890  | 31.8% |
| 1      | Yes     | 190     | 0.1%  |
| .      | Missing | 115,509 | 68.1% |
|        |         | 169,589 |       |

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**Gall bladder disease**

Since your last contact has a doctor told you that you had gall bladder disease?

**Variable #** 29**Sas Name:** GALLBLAD**Sas Label:** Gall bladder disease**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Other Disease/Condition

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 10,466  | 6.2%  |
| 1      | Yes     | 59      | 0.0%  |
| .      | Missing | 159,064 | 93.8% |
|        |         | 169,589 |       |

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**Problems with your pancreas**

Since your last contact has a doctor told you that you had problems with your pancreas?

**Variable #** 30

**Sas Name:** PANCREAS

**Sas Label:** Problems with your pancreas

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Medical History: Other Disease/Condition

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 10,504  | 6.2%  |
| 1      | Yes     | 14      | 0.0%  |
| .      | Missing | 159,071 | 93.8% |
|        |         | 169,589 |       |

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**Participant advised to continue study medications**

Resulting action from participant reports of symptoms or concerns: Participant reassured and advised to continue with current study medications.

**Variable #** 31

**Sas Name:** CONTMEDS

**Sas Label:** Participant advised to continue study medications

**Usage Notes:** Not collected on all versions of Form 10.

**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 13,189  | 7.8%  |
| 1      | Yes     | 108,506 | 64.0% |
| .      | Missing | 47,894  | 28.2% |
|        |         | 169,589 |       |

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**Participant advised to return for evaluation**

Resulting action from participant reports of symptoms or concerns: Participant advised to return to clinic for evaluation.

**Variable #** 32

**Sas Name:** RTRNEVAL

**Sas Label:** Participant advised to return for evaluation

**Usage Notes:** Not collected on all versions of Form 10.

**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 120,918 | 71.3% |
| 1      | Yes     | 777     | 0.5%  |
| .      | Missing | 47,894  | 28.2% |
|        |         | 169,589 |       |

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**Consulting gynecologist notified**

Resulting action from participant reports of symptoms or concerns: Consulting gynecologist notified.

**Variable #** 33

**Sas Name:** GYNNOTE

**Sas Label:** Consulting gynecologist notified

**Usage Notes:** Not collected on all versions of Form 10.

**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 119,471 | 70.4% |
| 1      | Yes     | 2,224   | 1.3%  |
| .      | Missing | 47,894  | 28.2% |
|        |         | 169,589 |       |

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Participant referred to primary physician

Resulting action from participant reports of symptoms or concerns: Participant referred to primary physician.

Variable # 34

Sas Name: PHYSNOTE

Sas Label: Participant referred to primary physician

Usage Notes: Not collected on all versions of Form 10.

Categories: Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 121,003 | 71.4% |
| 1      | Yes     | 692     | 0.4%  |
| .      | Missing | 47,894  | 28.2% |
|        |         | 169,589 |       |

Medications changed or stopped

Resulting action from participant reports of symptoms or concerns: Medications changed or stopped.

Variable # 35

Sas Name: MEDCHNG

Sas Label: Medications changed or stopped

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 115,672 | 68.2% |
| 1      | Yes     | 4,657   | 2.7%  |
| .      | Missing | 49,260  | 29.0% |
|        |         | 169,589 |       |

Other action taken

Resulting action from participant reports of symptoms or concerns: Other.

Variable # 36

Sas Name: OTHERACT

Sas Label: Other action taken

Usage Notes: Not collected on all versions of Form 10.

Categories: Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 112,221 | 66.2% |
| 1      | Yes     | 9,474   | 5.6%  |
| .      | Missing | 47,894  | 28.2% |
|        |         | 169,589 |       |

**How often did you take the study pills**

Since your last contact, how often did you take the study pills?

**Variable #** 37**Sas Name:** PILLFREQ**Sas Label:** How often did you take the study pills**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |                         | N       | %     |
|--------|-------------------------|---------|-------|
| 0      | Not at all              | 12,914  | 7.6%  |
| 1      | Less than once per week | 340     | 0.2%  |
| 2      | 1 - 2 days per week     | 468     | 0.3%  |
| 3      | 3 - 4 days per week     | 3,128   | 1.8%  |
| 4      | 5 - 6 days per week     | 5,260   | 3.1%  |
| 5      | Every day of the week   | 139,266 | 82.1% |
| .      | Missing                 | 8,213   | 4.8%  |
|        |                         | 169,589 |       |

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**How many days missed taking pills in last month**

About how many days have you missed taking your pills in the last month?

**Variable #** 38**Sas Name:** DAYSMISS**Sas Label:** How many days missed taking pills in last month**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| N      | Min | Max | Mean    | Std Dev |
|--------|-----|-----|---------|---------|
| 147119 | 0   | 31  | 3.01349 | 7.89883 |

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**Took all pills every day**

If there were days you did not take the pills, what were the reasons you didn't: Took all pills every day

**Variable #** 39**Sas Name:** ALLPILLS**Sas Label:** Took all pills every day**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 53,419  | 31.5% |
| 1      | Yes     | 94,588  | 55.8% |
| .      | Missing | 21,582  | 12.7% |
|        |         | 169,589 |       |

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**Experienced symptoms**

If there were days you did not take the pills, what were the reasons you didn't: Experienced symptoms

**Variable #** 40**Sas Name:** EXPSYMP**Sas Label:** Experienced symptoms**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 145,864 | 86.0% |
| 1      | Yes     | 2,143   | 1.3%  |
| .      | Missing | 21,582  | 12.7% |
|        |         | 169,589 |       |

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**Forgot pill(s)**

If there were days you did not take the pills, what were the reasons you didn't: Forgot pill(s)

**Variable #** 41**Sas Name:** FRGTPILL**Sas Label:** Forgot pill(s)**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 115,820 | 68.3% |
| 1      | Yes     | 32,187  | 19.0% |
| .      | Missing | 21,582  | 12.7% |
|        |         | 169,589 |       |

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**Forgot bottle**

If there were days you did not take the pills, what were the reasons you didn't: Forgot bottle

**Variable #** 42**Sas Name:** FRGTBOTL**Sas Label:** Forgot bottle**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 146,124 | 86.2% |
| 1      | Yes     | 1,883   | 1.1%  |
| .      | Missing | 21,582  | 12.7% |
|        |         | 169,589 |       |

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**Needed/Took a break**

If there were days you did not take the pills, what were the reasons you didn't: Needed/Took a break

**Variable #** 43**Sas Name:** TOOKBRK**Sas Label:** Needed/Took a break**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 146,981 | 86.7% |
| 1      | Yes     | 1,026   | 0.6%  |
| .      | Missing | 21,582  | 12.7% |
|        |         | 169,589 |       |

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**Afraid of health problems**

If there were days you did not take the pills, what were the reasons you didn't: Afraid of health problems

**Variable #** 44**Sas Name:** AFRAID**Sas Label:** Afraid of health problems**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 146,780 | 86.6% |
| 1      | Yes     | 1,227   | 0.7%  |
| .      | Missing | 21,582  | 12.7% |
|        |         | 169,589 |       |

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**Family/Friend recommendation**

If there were days you did not take the pills, what were the reasons you didn't: Family/Friend recommendation

**Variable #** 45**Sas Name:** FAMRCMND**Sas Label:** Family/Friend recommendation**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 147,950 | 87.2% |
| 1      | Yes     | 57      | 0.0%  |
| .      | Missing | 21,582  | 12.7% |
|        |         | 169,589 |       |

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**MD recommendation**

If there were days you did not take the pills, what were the reasons you didn't: MD recommendation

**Variable #** 46**Sas Name:** MDRCMND**Sas Label:** MD recommendation**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 145,407 | 85.7% |
| 1      | Yes     | 2,600   | 1.5%  |
| .      | Missing | 21,582  | 12.7% |
|        |         | 169,589 |       |

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**Didn't have any pills**

If there were days you did not take the pills, what were the reasons you didn't: Didn't have any pills

**Variable #** 47**Sas Name:** NOPILLS**Sas Label:** Didn't have any pills**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 145,906 | 86.0% |
| 1      | Yes     | 2,101   | 1.2%  |
| .      | Missing | 21,582  | 12.7% |
|        |         | 169,589 |       |

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**Other reason for missing pills**

If there were days you did not take the pills, what were the reasons you didn't: Other

**Variable #** 48**Sas Name:** OTHRMISS**Sas Label:** Other reason for missing pills**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 128,943 | 76.0% |
| 1      | Yes     | 19,064  | 11.2% |
| .      | Missing | 21,582  | 12.7% |
|        |         | 169,589 |       |

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Form 10 & 50 - HRT Management and Safety Interview, Report of Vaginal Bleeding

Data File: f10\_50\_ep\_fu\_pub File Date: 07/18/2005 Structure: Multiple rows per participant Population: E+P participants

Should be put on Intensive Adherence Program

Should participant be put on Intensive Adherence Program (IAP)?

Variable # 49

Sas Name: IAP

Sas Label: Should be put on Intensive Adherence Program

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 142,338 | 83.9% |
| 1      | Yes     | 2,797   | 1.6%  |
| .      | Missing | 24,454  | 14.4% |
|        |         | 169,589 |       |

Should participant be recontacted in one month

Should participant be recontacted in one month by phone for clinical follow-up

Variable # 50

Sas Name: RECONTAC

Sas Label: Should participant be recontacted in one month

Usage Notes: Not collected on all versions of Form 10.

Categories: Study Interventions: HRT Intervention/Management

| Values |         | N       | %     |
|--------|---------|---------|-------|
| 0      | No      | 128,490 | 75.8% |
| 1      | Yes     | 4,382   | 2.6%  |
| .      | Missing | 36,717  | 21.7% |
|        |         | 169,589 |       |